AMENDED IN SENATE MAY 23, 2003

AMENDED IN SENATE MAY 8, 2003

AMENDED IN SENATE APRIL 24, 2003

AMENDED IN SENATE APRIL 21, 2003

SENATE BILL

No. 506

Introduced by Senator Sher

February 20, 2003

An act to amend Section 4164 of the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 506, as amended, Sher. Pharmaceuticals: wholesalers and manufacturers' reporting requirements.

The Pharmacy Law, administered by the California State Board of Pharmacy in the Department of Consumer Affairs, makes it unlawful for any person other than a pharmacist to compound or dispense a dangerous drug or device, or to compound or dispense a prescription. Existing law provides exemptions from this prohibition for specified persons. A knowing violation of the Pharmacy Law is a crime.

Existing law requires wholesalers licensed by the board and manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into the state to report to the board all sales of dangerous drugs and controlled substances that are subject to abuse.

This bill would also require these wholesalers and manufacturers to report to the board specified information on all sales of antibiotics. The bill would require the board, beginning on January 1, 2006, to compile

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annually the information and to provide on its Web site notice of its availability. The bill would require the board to aggregate data where possible if disclosure would reveal legitimate confidential business information of an individual company. The bill would authorize the board to impose fees on wholesalers and manufacturers subject to these provisions and would prohibit the fees from exceeding its costs in implementing the provisions.

Because violations of this bill would be a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4164 of the Business and Professions 2 Code is amended to read:
- 4164. (a) All wholesalers licensed by the board and all manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.
 - (b) Notwithstanding subdivision (a), all wholesalers licensed by the board and all manufacturers who distribute dangerous drugs or dangerous devices within this state shall report to the board all sales of antibiotics in a time and manner chosen by the board. The report shall include, but is not limited to, all of the following:
 - (1) The identity of the antibiotic, including its generic and trade name.
 - (2) The market status of the antibiotic.
 - (3) The claimed use and targeted use of the antibiotic.
- 17 (4) Any other information the board deems appropriate.
- 18 (c) Beginning on January 1, 2006, and annually thereafter, the
- 19 board shall compile this information, and provide notice on its
- 20 Web site that the information is available.

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(d) If disclosure, as required in subdivision (b), of antibiotic sales data for an individual company would reveal legitimate confidential business information, the board shall aggregate the data where possible to avoid disclosure of that confidential business information. Any personal identifying information accompanying the antibiotic sales data shall remain confidential.

- (e) The board may impose fees on wholesalers and manufacturers subject to this section. The fees may not exceed the amount of the board's costs of collecting, collating, and disseminating information pursuant to this section.
- SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.